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EXAMINER

KIM, VICKIE Y

ART UNIT PAPER NUMBER

1614

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,268

Applicant(s)

TAKAHASHI ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,23-28 and 44-47 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,23-26 and 44-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7,27 and 28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/28/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed 11/21/2003. Upon entering the amendment, the claims 1, 3-4, 7 and 27-28 are amended and the claims 2, 8-22,29-43 and 48-49 are canceled.
2. The claims 1, 3-7, 23-28 and 44-47 are pending. However, only the elected claims 1, 3-4, 7 and 27-28 are presented for the examination and the non-elected claims are maintained as withdrawn.

Response to Arguments

3. Applicant's arguments with respect to claims 1, 3-4, 7 and 27-28 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

4. Claim1 is objected to because of the following informalities: "minoidil" in line 5 seems incorrectly spelled whereas the correct spelling would have been "minoxidil". Appropriate correction is required.

Claim Rejections - 35 USC § 112(1st)

New matter

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 3-4, 7, 27-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 is directed to a hair-growing agent comprising one or more members selected from the group consisting of lysophosphatidic acid, and phosphatidic acids having a straight chain fatty acid residue (2-24 of carbon atoms), where minoxidil is excluded. However, this negative limitation(i.e. exclusion of minoxidil) that rendered the claim indefinite because it was an attempt to claim the invention by excluding what the inventors did not invent rather than distinctly and particularly pointing out what they did invent. *In re Schechter*, 205 F.2d 185, 98 USPQ 144 (CCPA 1953). Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement, see MPEP 2173.05(i).

Thus, claim 1 and the dependent claims 3-4, 7, 27-28 are properly included in this rejection.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3-4, 7 and 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Bombardelli(US 5,484,833).

The claim is drawn to a composition comprising, as active ingredients, only one or more members selected from the group consisting of lysophosphatidic acids, and phosphatidic acids(PA) having a fatty acid residue moiety that consists of straight chain fatty acid residues having an even number of carbon atoms, said number being in the range of 2 to 24, where minoxidil is excluded.

Bombardelli(US'833, hereafter) teaches a composition comprising a phosphatidic acid(PA) having C₁₀₋₂₄ alkyl group, preferably C₁₅ or C₁₇, on a part of fatty acid moiety, see column 2, lines 7-22. For example, US'833 uses dipalmitoyl phosphatidic acid which has two fatty acids moieties with C₁₅-straight alkyl chain substituted, see table 1. Thus, all the critical elements required by the instant claims are taught and thus, the claims are not patentably distinct over the prior art of the record.

As to claims 3-4(0.01-5% PA required) and 27-28(0.01-1% of PA required), US'833 teaches 10-2000mg of the phosphatides(salt form) as an effective dose used in the treatment. In the examples I-III at column 5, any skilled artisan would have determined the effective dose of phosphatidic acids(among the salt form) used in the preparation of the oily lotion. For example, topical oily lotion(example III) contains 0.5g of the phosphatidate(the salt of phosphatidic acid and prioxicam). Any skilled artisan immediately understands that about 0.3g of phosphatidic acids is used to 0.5g of salt

when the examples I or II are learned. One would have been readily envisaged that about 0.6% of phosphatidic acids are used to make 50ml formulation of example 3. Thus, all the limitations recited in the claims 3-4 and 27-28 are embraced by the teaching of the cited reference.

It is noted that the recitation(i.e. hair growing agent) has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

It also noted that C₁₅ or C₁₇ alkyl substitution on fatty acid moiety makes fatty acid residue with even carbon numbers such as C₁₆ or C₁₈ fatty acid, respectively. Thus, the composition comprising only one or more phosphatidic acids with C₁₅ or C₁₇ alkyl substitution on fatty acid moiety anticipates the instant claims and not patentably distinct over the prior art of the record.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. Claims 1,3-4,7,27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kastell(US 4,515,778) in view of Touitou(US 5,716,638) and Bombardelli(US 5,484,833).

Kastell(US'778, hereafter) teaches a preparation for conditioning and grooming the hair, comprising phosphatidic acids as active ingredients, see abstract and example 1.

Applicant's claims differ mainly because they require phosphatidic acids(PA) having even number carbon atoms containing fatty acid residues and the specific amount of the phosphatidic acids.

Touitou(US'638, hereafter) teaches a cosmetic or medical composition for topical application to the skin. Comprising 0.5-10% of phospholipids(e.g. phosphatidic acid(PA)) as an essential component.

As mentioned earlier in 102 rejection, Bombardelli(US'833) teaches a topical preparation comprising phosphatidic acids(PA) as active ingredients wherein the PAs contain fatty acid residue with even number carbon atoms, preferably, C16 or C18 fatty acid containing PA.

Thus, when these references are taken together, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify US'778 composition to make therapeutically effective and cost efficient cosmetic or medical composition containing only one or more phosphatidic acids having C16 and/or C18 fatty acid(s) as active ingredients wherein the therapeutically amount of the acids used

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is in the range of about 0.5-1% because US'638 or US'833 teaches the deficiencies of US'778 teaching.

One would have been motivated to make such modification because it is always desired and good medical practice to choose most effective product where the therapeutic effectiveness and the safety have been well proven by the prior art of the record. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1,3-4, 7 and 27-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 17 of U.S. Patent No. 6,562,804. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the instant claims, now

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amended, is encompassed by the patented claims because the patented claims are directed to a hair growing agent comprising a phosphatidic acid having fatty acid residue with alkyl or alkenyl substituted on R1 and R2 position, especially methyl on R1 position, see claims. It is noted that the determination of effective dose of active ingredients are well within the skilled level of the ordinary skilled artisan. In light of the specification, the effective dose used in the claimed invention is well embraced by the range of 0.01-5% of PA. Furthermore, the patented claim 17 substantially excludes minoxidil. Thus, the instant claims are not patentably distinct over the cited patent.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579(fax: 571-273-0579). The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

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 **VICKIE KIM**
PRIMARY EXAMINER

Vickie Kim
April 17, 2004
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